

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Rodrigo CHUAQUI et al.

Appl. No. 09/743,825

Confirmation No. 8611

Filed: January 15, 2002

For: PB39, A GENE DYSREGULATED IN  
PROSTATE CANCER, AND USES  
THEREOF

Art Unit: 1642

Examiner: Minh-Tam DAVIS

Atty. Docket No. 31978-202420

Customer No.

45323

PATENT TRADEMARK OFFICE

DECLARATION UNDER 37 C.F.R. § 1.131

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

I, the undersigned, being duly warned, declare the following:

1. I am an inventor of subject matter described and claimed in the above-identified U.S. patent application.
2. The following experiment, recorded in the attached laboratory record page (Exhibit A), was conducted under my direction and/or the direction of Dr. Lance Liotta or Dr. Michael Emmert-Buck, who are a co-inventors of the subject matter claimed in the above-referenced U.S. application. The experiments were performed prior to May 22, 1998.
3. Exhibit A is page from a laboratory notebook (date has been redacted) which shows a nucleic acid sequence determined for a cDNA for the gene encoding PB39; the sequence

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includes sequences which encode the protein, as well as 5' and 3' un-translated flanking sequences.

4. The sequence shown in Exhibit A is a species of the genus set forth in the patent application of sequences of nucleic acid molecules which hybridize specifically with a nucleic acid molecule having a complete complement of the sequence of SEQ ID NO:1.


5. The Examiner, in the Office Action dated May 5, 2005, alleges that a sequence in WO98/21328-A2, published May 22, 1998, is allegedly 99.5% identical to SEQ ID NO:1 and allegedly anticipates "a purified nucleic acid molecule that comprises a fragment of the sequence of SEQ ID NO: 1, wherein said fragment hybridizes specifically with SEQ ID NO:1 (claim 18)."

6. It is noted that amended claim 18 recites, *i.e.*, "a purified nucleic acid molecule that consists of a fragment of the sequence of SEQ ID NO: 1, wherein said fragment hybridizes specifically with a nucleic acid molecule having a sequence that is completely complementary to SEQ ID NO: 1." New claim 21 recites: (A) a nucleic acid molecule that comprises a sequence that hybridizes specifically with a nucleic acid molecule consisting of the sequence of SEQ ID NO: 1, or (B) a nucleic acid that comprises a sequence that is completely complementary to the sequence of said nucleic acid molecule (A)."

7. The results described above and documented in Exhibit A shows possession of a nucleic acid falling within new claim 21, prior to the May 22, 1998 earliest effective date for the WO98/21328-A2 reference.

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

11/4/04  
Date

  
Rodrigo F. Chuaqui, MD

\_\_\_\_\_  
Date

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Lance A. Liotta, MD, Ph.D

\_\_\_\_\_  
Date

\_\_\_\_\_  
Kristina A. Cole, MD, Ph.D.

11/3/04  
Date

  
Michael R. Emmert-Buck, MD, Ph.D.

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8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

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Date

11-5-04  
Date

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Rodrigo F. Chuaqui, MD

Lance Liotta  
Lance A. Liotta, MD, Ph.D

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Date

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Kristina A. Cole, MD, Ph.D.

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Date

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Michael R. Emmert-Buck, MD, Ph.D.

\\ODMA\PC\DOCS\DC2\DOCS1\594203\1

these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

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Date

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Rodrigo F. Chuaqui, MD

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Date

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Lance A. Liotta, MD, Ph.D

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Date

11/5/04

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Kristina A. Cole, MD, Ph.D.

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Date

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Michael R. Emmert-Buck, MD, Ph.D.

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AA Sequence of PB39 (559 AA)



1680 nt between ATG and TAG (including TAG)  
562 nt 3' UTR

Length: 2307 [REDACTED] 18:08 Type: N Check: 5833 ..

1 tttttttttt ggagkgcaaa gcctggtgcc cggagccttg cggagytsgg

51 ggcacgcatg gccccacgc tgcaacaggc gtaccggagg cgctgggtgga

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